OCT 18 2011

SECTION 2 – 510(k) SUMMARY

Abdominal Aortic Tourniquet

Submitter's Name and Address:

John Croushorn, M.D.
Compression Works LLC
1634-A Montgomery Hwy #115
Hoover, AL 35216

Telephone: 205-202-1126
e-mail: jcroushorn@gmail.com

Contact Person

Ruth C. Forstadt, RAC
Regulatory Affairs Consultant to Compression Works LLC

Telephone: 401-521-3294
e-mail: rcforstadt@hotmail.com

Date Prepared: October 6, 2011

Name of Medical Device

Classification Name: Vascular Clamp

Common/Usual Name: Vascular Clamp

Proprietary Name: Abdominal Aortic Tourniquet (AAT)

Substantial Equivalence

The Abdominal Aortic Tourniquet is substantially equivalent to:

Combat Medical System's Combat Ready Clamp (K102025) and the Zimmer A.T. S. Automatic Pneumatic Tourniquet System (K012632).

Device Classification

This device carries an FDA product code DXC, and is classified as a Vascular Clamp under 21 CFR 870.4450.

Device Description

The Abdominal Aortic Tourniquet is a wedge shaped bladder that when inflated pushes in on the lower abdomen compressing all the structures within to include the descending aorta. The Abdominal Aortic Tourniquet (AAT) is designed to be used by military medical personnel in the battlefield to control bleeding in the inguinal area where standard tourniquets cannot be used. The device may be used instead of "mechanical pressure", allowing the medic to attend to other injuries or soldiers. The Abdominal Aortic Tourniquet is used to control a difficult bleed for up to 60 minutes until the injured soldier can be transferred to evacuation personnel for further treatment.

Indications for Use

The Abdominal Aortic Tourniquet is indicated for use in the battlefield to control difficult bleeds in the inguinal area.

Technological Comparison to Predicate Devices

	Proposed AAT Device	Predicate Combat Ready Clamp	Predicate A.T.S. Automatic Tourniquet System
Configuration	Inflatable pneumatic tourniquet	Expandable aluminum clamp	Inflatable pneumatic tourniquet
Method of Action	Manual	Manual	Automatic
Components	Waistband (belt and cumberband), inflatable air bladder (pneumatic inflator), manual pump	Base plate, vertical and horizontal arms, pressure handle, pressure disc, adjustable strap	Control unit, pneumatic tourniquet cuff, connector tubing from control unit to cuff

Safety and Performance

Results of performance and safety testing have demonstrated that the device is substantially equivalent to the predicate devices.

Non-clinical testing included burst pressure testing on the bench, as well as animal testing. The animal testing was performed in eight (8) swine animals to evaluate the mechanical efficacy of the Abdominal Aortic Tourniquet device to significantly decrease or halt blood flow in the abdominal aorta for 60 minutes without causing tissue damage. Mean arterial pressure (MAP), central venous pressure (CVP), intra-abdominal pressure, potassium levels, lactate levels were measured and tissue histology was completed. Flow was essentially undetectable in the femoral catheter during the tourniquet application. Serum potassium and lactate did not reach clinically significant numbers. Gross and histological examination revealed no signs of significant ischemia or necrosis of the small and large intestine. The Abdominal Aortic Tourniquet was determined to be substantially equivalent to the predicate devices in decreasing or eliminating blood flow.

A human data study in nine (9) subjects was performed to measure the pressure required in the Abdominal Aortic Tourniquet to reduce or cease blood flow in the common femoral artery (CFA) and the discomfort caused to the subject during the procedure. Pulsed-wave Doppler was used to measure the flow in the CFA every 30mmHG as measured on the Abdominal Aortic Tourniquet manometer. Discomfort was measured using the verbal 1-10 pain scale. The average pressure required to cease flow was 191mmHg with a minimum of 150mmHg and maximum of 230mmHg. The average discomfort at cessation of flow was 6.6 with a minimum of 4 and maximum of 10. All discomfort ceased when the device was released. The Abdominal Aortic Tourniquet device was determined to be substantially equivalent to the predicate devices in decreasing or eliminating blood flow in the CFA.

Based on the indications for use, technological characteristics, and comparison to predicate devices, the Abdominal Aortic Tourniquet has been shown to be substantially equivalent to predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

OCT 18 2011

Compression Works LLC.
c/o Ruth Forstadt
15 Sargent Ave.
Providence, RI 02906

Re: K112384
Trade/Device Name: Abdominal Aortic Tourniquet
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II (two)
Product Code: DXC
Dated: September 27, 2011
Received: October 4, 2011

Dear Ms. Forstadt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K112384

Device Name: Abdominal Aortic Tourniquet

Indications for Use:

The Abdominal Aortic Tourniquet is indicated for use in the battlefield to control difficult bleeds in the inguinal area.

Prescription Use ____x___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K112384